HASQARD Focus Group
Meeting Minutes
March 18, 2014

The meeting was called to order by Huei Meznarich, HASQARD Focus Group Chair at 2:05 PM on March 18, 2014 in Conference Room 308 at 2420 Stevens.

Those attending were: Huei Meznarich (Focus Group Chair), Cliff Watkins (Focus Group Secretary), Joe Archuleta, Glen Clark, Robert Elkins, Scot Fitzgerald, Joan Kessner, Mary McCormick-Barger, Karl Pool, Noe'l Smith-Jackson, Rich Weiss, and Eric Wyse.

I. Huei Meznarich asked if there were any comments on the minutes from the February 25, 2014 meeting. No Focus Group members stated they had additional comments on the February meeting minutes and, after hearing a motion and second for approval, the minutes were approved.

II. A discussion of the latest efforts to complete Revision 4 of HASQARD was held:

a. The Focus Group members present revisited the discussion of quality control acceptance criteria for the SW-846 inorganic methods in the most recent Update V as published in the Federal Register (October 23, 2013) and the appropriateness of incorporating some of the new criteria in revision 4 of Volume 4, Table 6-2. The Focus Group received the proposed revision to Table 6-2 along with a summary of the EPA method changes after the February meeting. No issues with the proposal were identified. Rich Weiss stated that the prosed revision is less prescriptive than the criteria in the new DOE/DOD Quality Systems Manual (QSM) that is being used by the DOE Consolidated Audit Program (DOECAP). The Focus Group members present concurred with the revision and its incorporation in the final draft of Volume 4 of HASQRD Revision 4.

b. The appropriate requirements for software QA in Volume 1 of HASQARD were discussed. Between the February and March meetings, Mary McCormick-Barger identified language in ANSI/ASQC E4 that she felt addressed the desire to ensure analytical instrument control software was not required to be tested other than through calibration of the instrument. The language in the E4 standard says, "Computer hardware/software configurations integral to measurement and/or testing equipment that are calibrated for a specific purpose do not require further testing unless the scope of the software usage changes or modifications are made to the hardware/software configuration." Huei Meznarich noted that this language mentions "further testing" when testing was not mentioned previously in the proposed language for the software QA section. Huei proposed the sentence be revised to, "Computer hardware/software

configurations integral to measurement and/or testing equipment that are calibrated for a specific purpose requires calibration and appropriate quality control per Volume 4 prior to use or tests as being adequate for use and do not require further testing unless the scope of the software usage changes or modifications are made to the hardware/software configuration." Robert Elkins reported he had researched this matter in the WRPS QA Program (TFC-TLN-02) and found that it discussed "embedded software." The WRPS QA Program also excuses "embedded software" from rigorous testing typical for newly developed software applications. The discussion of embedded software in the WRPS QA Program is in the section regarding vendor approval rather than in the software QA requirements section. The WRPS personnel and other Focus Group members present agreed that the term "embedded software" should be avoided in HASQARD as it could be confusing and concurred with the proposed language provided by Huei. Rich Weiss added that the proposed language is very appropriate for the common, routinely used instrumentation found in most analytical laboratories but cautioned that stricter requirements should still apply for an instrument that was new technology. The Focus Group members present realized such new technology is so rarely used, it need not be accounted for in the software QA language used in HASQARD.

The Focus Group discussed the proposed software QA language for Laboratory Information Managements Systems (LIMS). Specifically, the proposed language on assessments conducted on the LIMS was discussed. The proposed language is: "Annual assessments of the LIMS shall be performed to ensure the integrity of electronic data. Records of inspections shall be maintained and reports submitted to laboratory management, noting any problems identified with electronic data processing and stating the corrective actions taken to preclude recurrence." The questions were whether the frequency specified was appropriate and how a laboratory would go about such an assessment. Karl Pool stated that the Focus Group should consider the value added by this requirement as long as the laboratory ensures that any changes they make to their LIMS are evaluated at the time the change is made to ensure it does not result in errors. Representatives of QA from the WSCF and 222S laboratories stated that spot checks of the data in their LIMS are conducted routinely. The Focus Group members thought this requirement comes from the QSAS. After discussion, the Focus Group members agreed that the requirement does not add any value because the LIMS is being utilized very frequently (i.e., daily) and as a result issues would present themselves quickly. The requirement will be deleted. **NOTE**: following the meeting, the Secretary reviewed Revision 2.4 of the QSAS and found no requirement for annual assessment of LIMS data. A reference in the QSAS to assessments of electronic data states: "Periodic inspections of the

electronic operations shall be performed by the QA Organization to ensure the integrity of electronic data."

c. The language for the basis of requirements driving the HASQARD was discussed. This language is found in Section 1.0 of Volume 1. Mary McCormick-Barger stated that the current language (and language proposed for Revision 4 of Volume 1) does not appropriately indicate the importance of the Tri-Party Agreement (TPA) reference to HASQARD as a driver for its continued use at Hanford. Because of this, the Focus Group agreed to change the first paragraph of Section 1.0 to read:

"The *Hanford Analytical Services Quality Assurance Requirements Documents* (HASQARD) Volumes 1 through 4, are issued by the U.S. Department of Energy (DOE), Richland Operations Office (RL) and Office of River Protection (ORP). The HASQARD establishes quality requirements in response to DOE Order 414.1C or 414.1D, *Quality Assurance* (as applicable). The HASQARD satisfies the requirements from the *Hanford Federal Facility Agreement and Consent Order* (Tri-Party Agreement) (TPA) (Ecology et al 2002) Article XXXI and the TPA Action Plan, Sections 6.5 and 7.8. The HASQARD is designed to meet the needs of the Hanford Site for maintaining a consistent level of quality for sampling and for field and laboratory analytical services provided by contractor and commercial field and laboratory analytical operations."

d. The Focus Group discussed comments received from Chuck Soderquist of Battelle Pacific Northwest National Laboratory. Chuck had raised an issue to the Focus Group Chair and Secretary concerning Kinetic Phosphorescence Analysis (KPA) being placed in the Inorganics Analyses section of HASQARD Volume 4. After the Focus Group discussed the fact that KPA is operated under radiochemical principles and that detection limit can be determined by the counting statistics, the members present agreed to move KPA to the corresponding tables associated with the radiochemistry techniques (Tables 4-1 and 6-1). Mr. Soderquist's comments were shared with Rich Weiss who agreed with his position that KPA is a technique that uses counting statistics and reports uncertainty which are attributes more common to radiochemical methods than inorganic methods. The question was raised whether there is any text regarding QC criteria (e.g., method acceptance criteria) for KPA that would also need to be revised because of the decision to move the KPA to the radiochemistry section. Rich Weiss agreed to check this and ensure it is only the criteria in the tables that need to be moved to accommodate Mr. Soderquitst's request. The Focus Group also discussed the fact that many laboratories are discontinuing their KPA capability in favor of low activity determinations for uranium using Inductively Coupled Plasma/Mass

Spectrometry (ICP/MS).

e. Between the February and March meeting, Chris Sutton had suggested that Volume 3 and Volume 4 of HASQARD could possibly be combined in one volume. Chris's opinion came from the fact that by editing Volume 3 to make it consistent with Volume 4, it now repeats much of the same language. Glen Clark said he understands, but thinks the combining would create too much confusion and would involve too much new material to have it all in one volume. Huei Meznarich concurred with Glenn on this statement. Joan Kessner added that the two volumes are to be used by two very separate audiences and would prefer to see them remain separated. Rich Weiss agreed and stated that it would be confusing to people trying to explain why the material that used to be in Volume 4 is now called Volume 3 and for the sake of consistency alone the two volumes should be retained. The Focus Group members present agreed that this might be something worth looking at when Revision 5 of HASQARD is needed, but for Revision 4 agreed to retain four volumes.

f. The status of production of a final draft of Volume 4 for review was discussed. The issue has been the availability of the technical editor. The technical editor working on the final draft of Volume 4 has been out of the office on short term disability. Huei Meznarich stated that she is scheduled to return to work and should be able to help complete the editing on Volume 4 before the next HASQARD Focus Group meeting. Huei stated that the new QC criteria for inorganic analysis method blanks and placement KPA requirements in the tables will be addressed during final editing of Volume 4.

g. The Focus Group discussed the final draft of Volume 3. Much of the discussion concerned the fact that this draft uses the term "process monitoring" in addition to "field analyses" as activities to which the requirement in Volume 3 apply. The Waste Treatment Plant (WTP) analytical laboratory was discussed in the context of this terminology. To date, the WTP analytical laboratory has not participated in HASQARD development. To ensure any future involvement in HASQARD is not hindered by use of the term "process monitoring," Joan Kessner suggested a differentiation between process monitoring and process control. The WTP analytical laboratory will most likely be doing testing to support process control. The analyses at the groundwater pump and treat facilities are better termed process monitoring because they are conducted to monitor the effectiveness of an on-going remediation system.
Scot Fitzgerald agreed to look at the draft again and ensure process monitoring is called out in all of the appropriate places.

The breadth of application of Volume 3 was discussed. The question was asked about which companies represented on the Focus Group would

utilize Volume 3. The main user of Volume 3 will be CHPRC at the pump and treat facilities. Representatives from WCH stated they have eliminated almost all field testing to avoid waste generation in the field. In some cases, WCH has even sent samples to commercial laboratories for indicator analyses typically conducted using test strips to avoid waste generation. The only technique widely used in the field by WCH is x-ray fluorescence for metals since this technique generates no waste.

The Focus Group made very few comments on the draft of Volume 3 and those made were mainly editorial. The Focus Group completed reviewing Section 1-5 of Volume 3 before the allotted time for the meeting had been expended.

The Focus Group Chair suggested that the meeting be adjourned and that the group continue review of Volume 3 starting with Section 6 at the April meeting. Hearing no objections, the Chair adjourned the meeting at 4:19 PM.

The next meeting is scheduled for April 15, 2014 at 2:00 PM in 2420 Stevens, Room 308.